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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stewart Cole

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,021	Applicant(s) COLE ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,12-14,18-24,26,29,43-49,57,62,64 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,12-14,18-24,26,29,43-49,57,62,64 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**

2. Applicants' Response to Final Office Action, received 30 July 2008, is acknowledged.

Claims 1, 4, 5, 12, 13, 14, 18, 19, 24, 26, 29, 43, 44, 45, 46, 47, 48, 49, 57, 62, and 64 have been amended. New claim 72 has been added. Claims 7, 9-11, 25, 27, 28, 30-42, 50-56, 58-61, 63, and 65-71 have been canceled.

3. Claims 1, 4, 5, 12-14, 18-24, 26, 29, 43-49, 57, 62, 64, and 72 are pending and under consideration.

Rejections/Objections Moot or Withdrawn

4. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponds to", is moot in light of the cancellation of the claim.

5. The objection to claim 2 is moot in light of the claim being canceled.

6. The rejection of claims 70 and 71 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.

7. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for composition of deposited strains, is withdrawn in light of the amendment of the claims.

8. The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponding to", is withdrawn in light of the amendment of the claim.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4, 5, 12-14, 18-23, 29, 43-49, 57, 62, 64 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5, 14, 62, 64 and 72 recite "fragments thereof" of genes. Claim 20 recites "parts of the genes". However, there is no restriction on size of the fragments or parts and also there is no function designated for these fragments or parts.

Therefore, the claims are indefinite concerning the structure and function of "parts" and "fragments".

Claims 12, 13, 18, 19, 21-23, 29, 43-49 and 57 depend from the claims, but do not clarify the issue.

11. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a strain wherein the CFP-10 encoding gene is altered by directed mutagenesis in a way that "most of the immunogenic peptides" of CFP-10 "remain intact", but the biological functionality of CFP-10 is lost.

It is unclear how many and which peptides are included in "most of the immunogenic peptides" and what is the metes and bounds of "remain intact". In addition it is unclear how the biological functionality of CFP-10 is lost if the resulting polypeptide remains immunogenic, which is one biological functionality.

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12. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to an epitope "derived thereof". The specification does not define the term "derived" and therefore it is unclear what are the metes and bounds of the term.

13. Claims 48, 49 and 57 provide for the use of a bacterial strain, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

14. Claims 1, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is a strain of *M. bovis* BCG wherein said strain has integrated the DNA fragment RD1-2F9 which "comprises" 31,808 bp and which is designated as SEQ ID NO:1.

Claim 24 is drawn to an *M. bovis* BCG::RD1 stain which has integrated a cosmid "herein referred to as RD1-2F9".

Claim 26 is drawn to an *M. bovis* BCG::RD1 stain which has integrated "the" insert of the cosmid RD1-2F9, said cosmid "comprising" *M. tuberculosis* genome from ca. 4337 kb to ca. 4369, "having the sequence shown in SEQ ID NO:1".

The sequence listing defines that SEQ ID NO:1 as an "insert" of cosmid RD1-2F9.

Thus, it appears that each of the claims and the sequence listing are defining RD1-2F9 and SEQ ID NO:1 differently.

Therefore, it is unclear what sequence is actually being described in the claims.

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Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claims 48, 49 and 57 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 12, 2009